

# **Human Factors in Medical Device Use Safety**

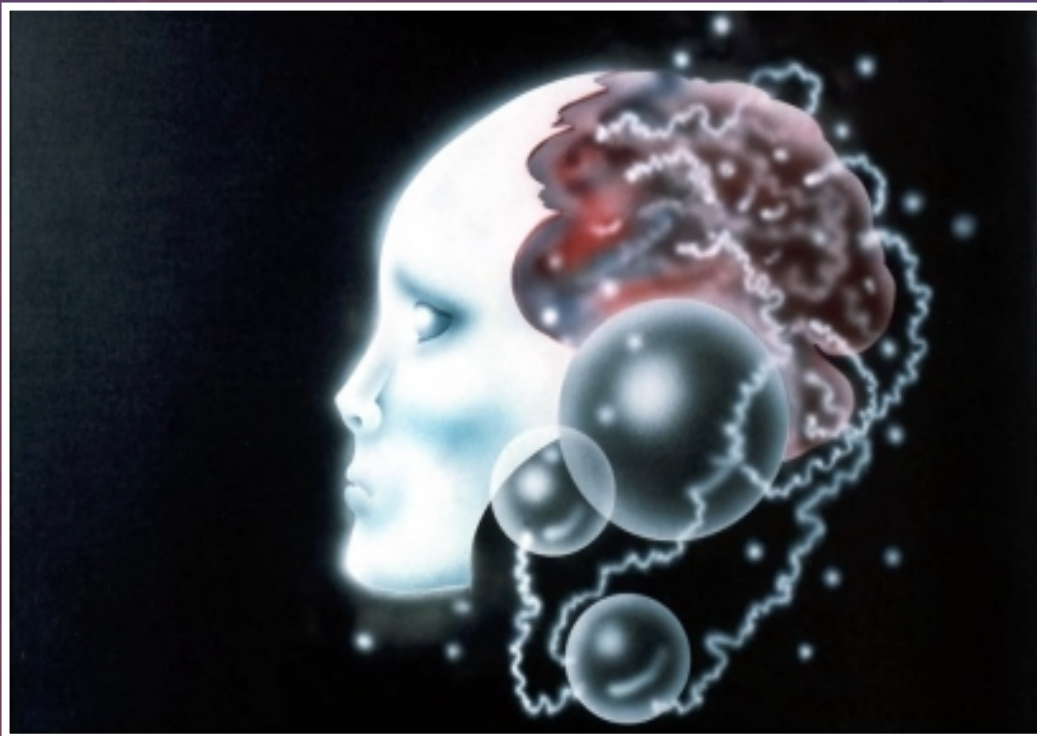
## **How to Meet the New Challenges**

**August, 2000  
Ron Kaye**



# Glimpse of the Future

- **New Medical Devices and Medical Devices of the Future**



DEVICE USER PROGRAMS  
FDA  
AND SYSTEMS ANALYSIS

# Challenges for HF

## Focus on Safety and Effectiveness

- Efficiency and productivity
- Information security “privacy and confidentiality issues”
- Safety and effectiveness issues

- Use-related problems

*Use problems => Use Errors => Hazards*

- Unintended and “off-label” use

# New Challenges Driving Factors

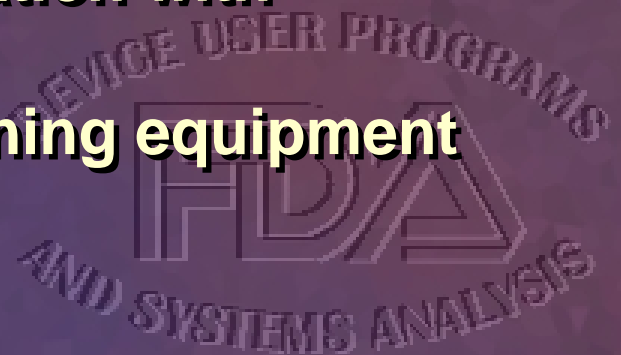
- ***Device use is Changing***
  - **Users are Changing**
  - **Environments are Changing**
  - **Devices are Changing**



# **New Challenges Driving Factors (Cont.)**

## **Users are Changing**

- **More lay users**
- **More aging users**
- **More users with less formal training**
- **New roles for patients as users**
  - **Participating in the selection of devices**
  - **Communication and coordination with healthcare providers**
  - **Troubleshooting and maintaining equipment**

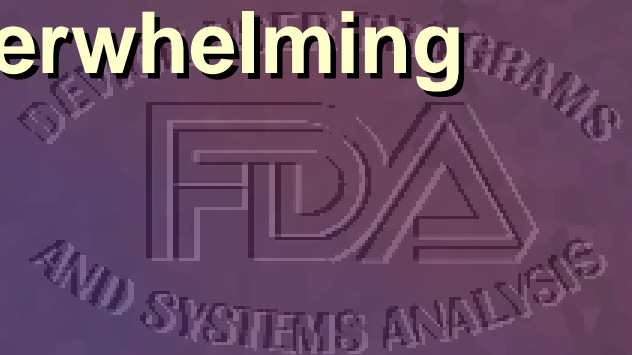


# **New Challenges**

## **Driving Factors (Cont.)**

### **Environments are Changing**

- **Home use (work, car, etc.)**
- **Out-patient use**
- **Faster paced environments “chaos”**
- **Multi-device, multi-configuration, rapidly changing environments at healthcare facilities “overwhelming flood of technology”**



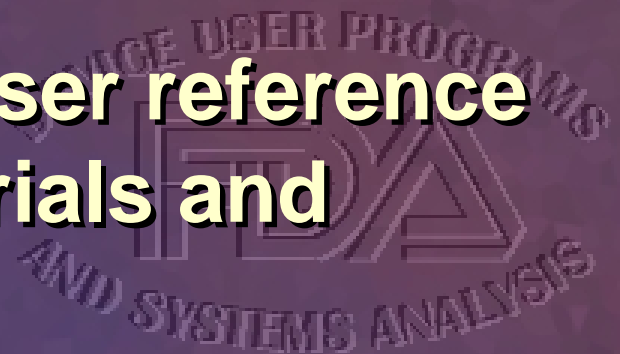


# **New Challenges**

## **Driving Factors (Concluded)**

### **Devices are Changing**

- **More capable**
- **More critical to health and survival**
- **More complex**
- **New and different demands on users**
- **Impacts complexity of user reference materials, training materials and importance of training**



# Medical Device Use Safety

Whose responsibility is it?

Who should improve it?

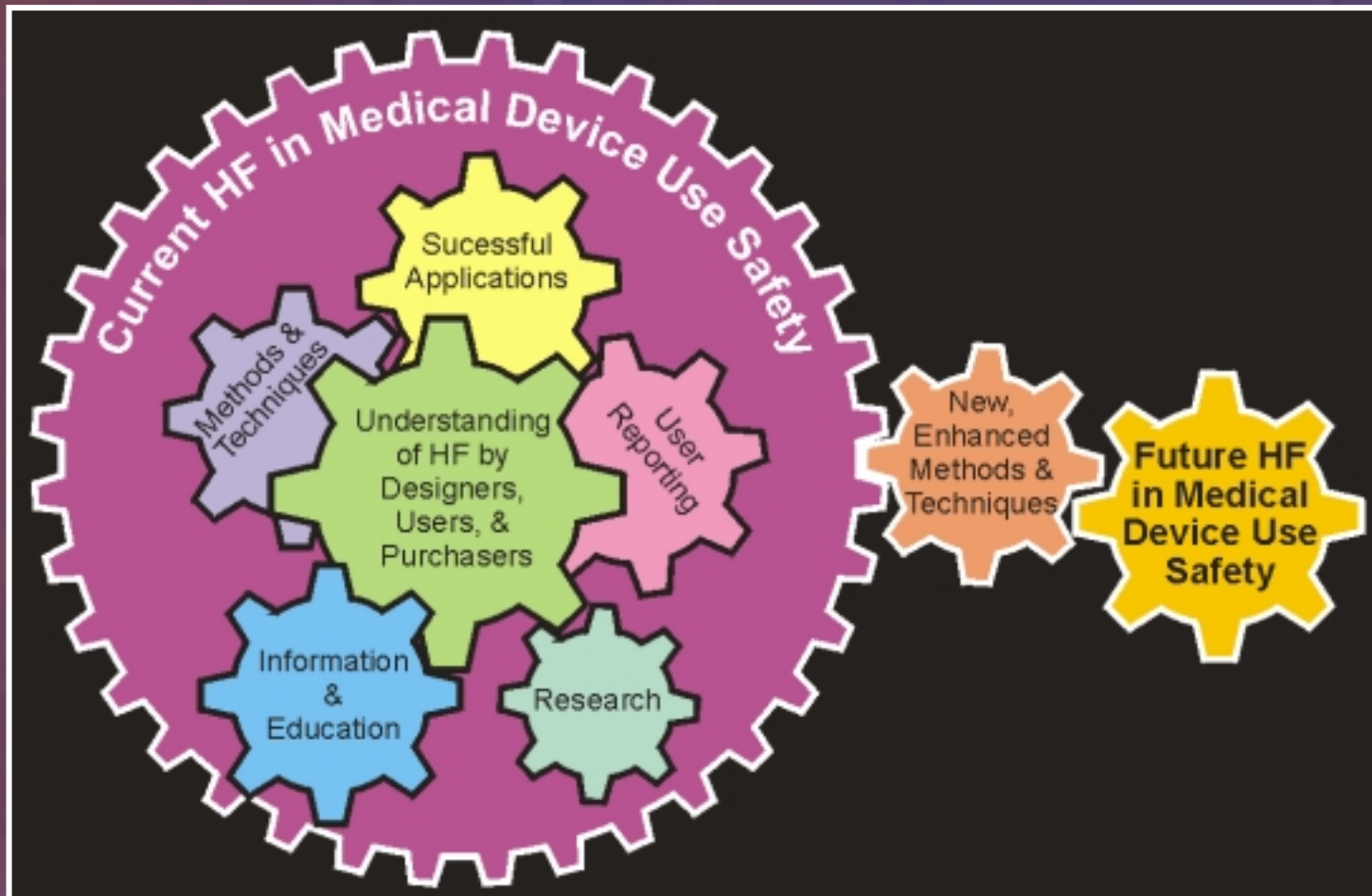


DEVICE USER PROGRAMS  
AND SYSTEMS ANALYSIS

The FDA logo is a circular emblem with the letters "FDA" in a large, bold, serif font in the center. The words "DEPARTMENT OF HEALTH AND HUMAN SERVICES" are written in a smaller, sans-serif font around the perimeter of the circle.



# The Mechanism for Meeting New HF Challenges



# **Meeting the New Challenges**

## **“Awareness” Issues**

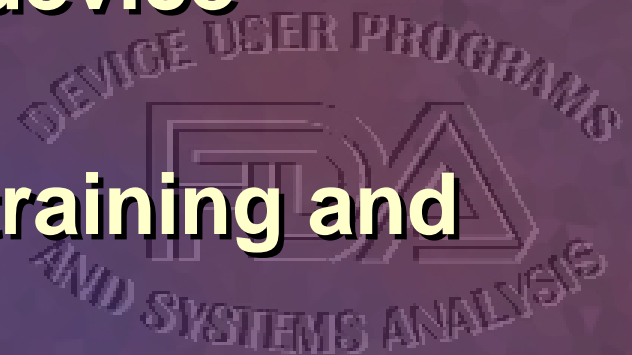
- **Focus HF emphasis on safety**
- **Increase awareness of HF and safety**
- **Encourage more useful reporting of use problems**
- **Address over-reliance**



# **Meeting the New Challenges**

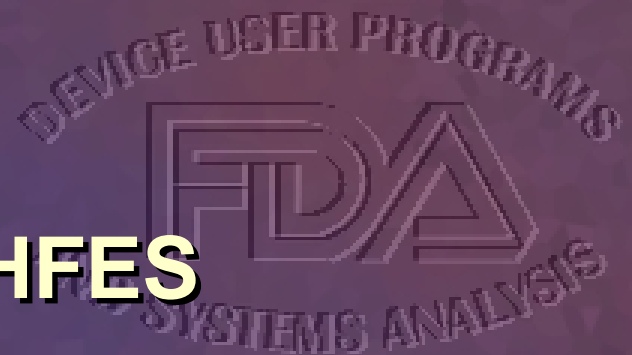
## **HF Technique Issues**

- **Sample realistic use effectively and efficiently**
- **Obtain high-quality feedback from users during device evaluation**
- **Analyze use problems effectively**
- **Assess user ability vs. device complexity**
- **Improve status of user training and instruction materials**



# **Roles for HFES Technical Group Expertise**

- **Knowledge and techniques to meet new and ongoing challenges to safety and effectiveness**
  - **Best if it results from work on medical devices**
    - **Relevance is clear**
    - **Not questionable**
- **All technical groups in HFES**



**\*Just Released\***  
**HF Guidance Document**

**Medical Device Use--Safety:  
Incorporating Human Factors Engineering  
into Risk Management**

Available at:

**<http://www.fda.gov/cdrh/HumanFactors.html>**

